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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,230	06/20/2003	Jack Q. Wilkinson	0325.210US	9796
27123	7590	03/09/2006	EXAMINER	
MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,230	WILKINSON ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6 and 9-13 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 9-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicants' election with traverse of Group 1, claims 1-4 and 9-13, and SEQ ID NO:1 in the reply filed on December 2, 2005 is acknowledged. The traversal is on the ground(s) that claim 6 can be included in Group I without causing a serious burden to the Examiner, as claim 6 is drawn to a method for isolating recombinant protein from a plant cell, the recombinant protein being expressed from a recombinant expression cassette that has been transfected into a plant cell, and the recombinant expression cassette comprising a polynucleotide encoding the recombinant protein of interest linked to the 3' termination sequence of claim 1. Applicants point out that due to Applicants' election, the Examiner will be searching and examining claim 1 and maintain that as such, there is a link between the claims in Group I and claim 6. This is not found persuasive because although a search of Group I overlaps with a search of claim 6 with respect to the 3' termination sequence that is a component of the recombinant expression cassette claimed in Group I, the search of Group I and claim 6 are not coextensive, as a search of claim 6 also requires a search with respect to polynucleotides encoding recombinant proteins and their use with 3' termination sequences in plant cells for the purpose of recombinant protein expression and isolation, which search is not required for the claims of Group I. Accordingly claim 6 is withdrawn from consideration as being directed to a nonelected invention.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The abstract of the disclosure is objected to because it is not descriptive of the elected invention. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to the recombinant expression cassette of claim 1 wherein the 3' termination sequence has at least 70% identity to SEQ ID NO:1.

The specification describes a recombinant expression cassette comprising the 3' termination sequence of SEQ ID NO:1, a 485 bp nucleotide sequence obtained from the CAL1 gene of the yeast *Saccharomyces cerevisiae* that functions as a 3' termination sequence in plant

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cells (pages 56-59 and sequence listing). The specification does not describe other nucleotide sequences having at least 70% identity to SEQ ID NO:1 that function as a 3' termination sequence in plant cells.

The Federal Circuit has recently clarified the application of the written description requirement to polynucleotide sequences. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus which encompasses numerous undisclosed and uncharacterized variants having at least 70% identity to SEQ ID NO:1 that function as a 3' termination sequence in plant cells, nor the structural features unique to the genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 10-13, and claims 2, 3 and 9 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 10-13 are indefinite in reciting percent identity to nucleotide sequences identified only by organismal source. Percent identity to nucleotide sequences identified by organismal source alone cannot be

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determined, because nucleotide sequences have the same chemical composition (nucleotides) regardless of organismal source, such that determination of percent identity requires a comparison between the particular arrangement of nucleotides in the sequences being compared.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Rothnie H.M et al. (The contribution of AAUAAA and the upstream element UUUGUA to the efficiency of mRNA 3'-end formation in plants. EMBO J. 1994 May 1;13(9):2200-10).

The claims are drawn to a recombinant expression cassette comprising a virus promoter that is functional in plants operably linked with a coding sequence having a stop codon, the coding sequence being operably linked with a non-plant 3' termination sequence, wherein the non-plant termination sequence is heterologous to the coding sequence and comprises: a cleavage site including a nucleotide sequence YA defining a position of endonucleolytic cleavage and subsequent 3' polyadenylation; ii. a positioning element of 6 nucleotides located between 10 nucleotides and 40 nucleotides 5' of the cleavage site and with at least 4 out of 6 nucleotides being adenine; an upstream element that (a) is located between 1 nucleotide and 250 nucleotides 5' of the positioning element; and (b) comprises TAYRTA or two or more repeats of the TA, TG, or TA and TG where the repeats are separated by 0 to 10 nucleotides; and is a

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nucleotide sequence having at least 60% sequence identity to a native fungal or native animal 3' termination sequence and less than 90% sequence identity to native plant 3' termination sequence, wherein the cleavage site is flanked by a pair of thymidine-rich regions, each thymidine-rich region comprising at least 6 nucleotide pairs of at least 80% thymidine; and being within about 50 nucleotides of the cleavage site, and a recombinant plant cell comprising said expression cassette.

Rothnie H.M et al. teach a recombinant expression cassette comprising a CaMV 35S virus promoter that is functional in plants operably linked with a coding sequence having a stop codon, the coding sequence being operably linked with a CaMV non-plant 3' termination sequence, wherein the non-plant termination sequence is heterologous to the coding sequence and comprises: a cleavage site including a nucleotide sequence YA defining a position of endonucleolytic cleavage and subsequent 3' polyadenylation; ii. a positioning element of 6 nucleotides located between 10 nucleotides and 40 nucleotides 5' of the cleavage site and with at least 4 out of 6 nucleotides being adenine; an upstream element that (a) is located between 1 nucleotide and 250 nucleotides 5' of the positioning element; and (b) comprises TAYRTA or two or more repeats of the TA, TG, or TA and TG where the repeats are separated by 0 to 10 nucleotides; wherein the cleavage site is flanked by a pair of thymidine-rich regions, each thymidine-rich region comprising at least 6 nucleotide pairs of at least 80% thymidine; and being within about 50 nucleotides of the cleavage site, and recombinant *Nicotiana plumbaginifolia* plant cells comprising said expression cassette (page 2201 Figure 1; page 2202 column 1 first full paragraph). While Rothnie H.M et al. are silent with respect to whether the CaMV non-plant 3' termination sequence is a nucleotide sequence having at least 60% sequence identity to a

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native fungal or native animal 3' termination sequence and less than 90% sequence identity to native plant 3' termination sequence, Rothnie H.M et al. need not teach this limitation in order to anticipate the rejected claims, as the limitation is indefinite as set forth above in the rejection under 35 USC 112, second paragraph.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

 3/2/06

CC